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October 21, 2009

CERTIFIED MAIL
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Mr. Donald A. Heller
Corrective Action Section 1
Remediation and Reuse Branch
U.S.E.P.A., Region 5
77 W. Jackson Boulevard (LU-9J)
Chicago, Illinois 60604-3590

Re: Response to August 5, 2009 Memorandum from Daniel Mazur to Donald Heller Regarding Proposed Revision to Section 2.3 of the Draft CMS Report, May 2, 2008
Eli Lilly and Company, Tippecanoe Laboratories
IND 006 050 967

Dear Mr. Heller:

This cover letter and attached revised Corrective Measures Study (CMS) report language have been prepared in response to the August 5, 2009 Memorandum from Daniel Mazur to Donald Heller regarding proposed revision to Section 2.3 of the draft Corrective Measures Study Report.

The first paragraph of the August 5, 2009 memorandum states, "the revised report fails to use current U.S. EPA approved methods to develop water quality criteria that are protective of aquatic life." Eli Lilly and Company (Lilly) believes that the use of Great Lakes Initiative (GLI) water quality based effluent limitations (WQBELs), which were used by Lilly in developing the water quality criteria, are an accepted and appropriate methodology for the calculation of ecological criteria for the five compounds (n,n-diethylaniline, diethyl ether, hexane, tetrahydrofuran, and p-chlorobenzotrifluoride) for which U.S. EPA Region 5 Ecological Screening Levels (ESLs) are not established. Lilly reviewed the additional draft document and issue paper cited in the August 5, 2009 letter, but notes that these documents do not contain EPA approved methods for developing pore water or sediment criteria. Lilly proposes that the sediment pore water criteria be the same as the surface water criteria for these five compounds, just as U.S. EPA Region 5 ESLs are the same for both sediment pore water and surface water. As explained in more detail below, the secondary continuous criterion (SCC) is applicable in the surface water at the edge of the mixing zone, as provided in Indiana surface water regulations, rather than to the groundwater as proposed in the August 5, 2009 letter.

Within the second paragraph of the August 5, 2009 memorandum, it is stated "EPA correspondence...explains why the water quality criterion is the protective benchmark for sediment pore water and the contaminant concentration in the groundwater plume is expected to be the same as the sediment pore water." Lilly agrees with the first portion of this statement, that water quality criterion are the protective benchmark for sediment pore water. However, Lilly does not agree that the contaminant concentration in the groundwater plume is expected to be the same as the sediment pore water, as discussed in more detail below.

The concept that a benthic zone is not part of "groundwater" and is part of the surface water system is supported at the national level in programs and documents, such as "The Incidence and Severity of Sediment Contamination in Surface Waters of the United States, National Sediment Quality Survey: Second Edition" (USEPA-823-R-04-007, November 2004). In this document, it is stated that the U.S. EPA is required to "compile all existing information on the quantity, chemical, and physical composition, and geographic location of pollutants in *aquatic* sediments, including the probable sources of such pollutants and identification of those sediments which are contaminated...." (emphasis added). In addition, the U.S. EPA has been working on establishing methods and protocols for monitoring the physical, chemical, and biological effects of pollutants in aquatic sediment for more than 10 years.

For years, the U.S. EPA has acknowledged, as in the referenced document above, that there is substantial uncertainty and variability regarding the biological effects associated with chemical concentrations in sediments. Factors that influence potential effects include the following: (1) bioavailability, such as organic carbon level and sediment grain size; (2) interactive effects of chemical mixtures, which are nearly always present in contaminated sediment situations; and (3) analysis of biological receptors, including translation of effects from individual organisms to populations. Given these factors, the U.S. EPA has found that it is very difficult to derive a level of a substance that can be considered, based on sound science, to be appropriately protective of aquatic organisms, and has elected not to propose sediment criteria.

Therefore, Lilly does not believe that the Secondary Continuous Concentration (SCC) should be directly applied to groundwater. There is no reason to believe that concentrations present in sediment pore water would be the same as those present in groundwater. There is significant flushing back and forth both from surface water to groundwater, as well as from groundwater to surface water, which results in a transition zone between groundwater and surface water. The nature of this transition zone is adequately captured by the mixing zone concept within the GLI calculations. Therefore, as stated above, Lilly is proposing that the sediment pore water criteria be the same as the surface water criteria for these five compounds, just as U.S. EPA Region 5 ESLs are the same for both sediment pore water and surface water.

Lilly has addressed the enumerated comments within the August 5, 2009 letter, as follows:

1. Section 2.3 Groundwater POC End-Point Criteria, 2nd sentence, page 1

   Lilly has revised this sentence to reflect U.S. EPA's comment.

2. Section 2.3.2.1 Calculation of Secondary Continuous Concentrations, page 3, Table

   Lilly has revised the table to include the updated aquatic toxicity data as provided in U.S. EPA's comment.

3. Section 2.3.2.2 Calculation of Criteria for Wabash River, Pore Water Criteria, page 6

   As already discussed in this cover letter, Lilly is proposing that the sediment pore water criteria be the same as the surface water criteria for these five compounds, just as U.S. EPA Region 5 ESLs are the same for both sediment pore water and surface water.

4. Maximum acceptable toxicant concentration (MATC)

   Reference to MATC has been removed from Section 2.3.

5. Section 2.3.2.2 Calculation of Criteria for Wabash River, Pore Water Criteria, page 7

   This section of the report has been replaced by Appendix C 1.2.2.

6. Section 2.3.2.2 Calculation of Criteria for Wabash River, Pore Water Criteria, page 7

   This section of the report has been replaced by Appendix C 1.2.2.

7. Section 2.3.2.2 Calculation of Criteria for Wabash River, Pore Water Criteria, page 9 and 10

   This section of the report has been replaced by Appendix C 1.2.2.

Lilly appreciates your continued efforts as we work to finalize the CMS. As you are aware, end points must be agreed upon in order for Lilly to finalize a revised CMS report. I will contact you to arrange a teleconference to discuss this correspondence. Please contact me at 765-477-4361 if you have any questions or comments in the interim.

Sincerely,

Lucy S Wang

Lucy S. Wang
Associate Consultant

cc: Mario Mangino, Dan Mazur, David Petrovski – EPA/RRB
Paula Bansch, Doug Griffin – IDEM